Applicants appreciate the courtesy extended to them in an informal telephonic conference on May 15, 1997, with the Examiner. The claims have been amended to more clearly define that the antigens of the inventions are encoded by the restriction fragments of plasmid λ-J19 as suggested by the Examiner in the telephonic conference. No new matter is added by these amendments.

Claims 23, 32, and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner indicates that the specification allegedly does not provide demonstrative evidence that applicants were in possession of the claimed HIV-1 antigens and that the methods for the production and recovery of HIV-1 specific antibodies were adequately described. It is stated that the enablement rejection is withdrawn since it is conceded that the availability of the complete nucleotide sequence of the λ-J19 proviral clone enables the skilled artisan to produce viral antigens from the claimed restriction fragments. However, it is stated that since this information was not available to the skilled artisan until January, 1985, and was not disclosed in those applications filed prior to this date, priority cannot be extended to those applications filed prior to this date. It is concluded that the priority date of the instantly claimed invention will be extended to the filing date of S.N. 06/706,562, filed February 28, 1985. Applicants respectfully traverse the rejection.

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The function of the written description requirement under the first paragraph of 35 U.S.C. § 112 is to clearly convey the subject matter that an applicant has invented as of the filing date of the application relied on. In re Barker, 559 F.2d 588, 592 n.4, 194 U.S.P.Q. 470, 473 n.4 (C.C.P.A. 1977), cert. denied, 434 U.S. 1064 (1978). The applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he was in possession of the invention, i.e., whatever is now claimed. Vas-Cath Inc. v. Mahurkar, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

The date of deposit for plasmid λ-J19 is immaterial to a written description requirement. To the contrary, the time for making an original deposit is specified in 37 C.F.R. § 1.804 and is reiterated in pertinent part for the convenience of the Examiner:

> 37 C.F.R. 1.808 Time of making an original deposit.
> (a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made **at any time before filing the application for patent or, subject to § 1.809, during pendency of the application for patent.**

(Emphasis supplied). Accordingly, the time for making the deposit of the plasmid λ-J19 may be made at any time during the pendency of the application.

Furthermore, applicants submit that the actual deposit date of the plasmid λ-J19 is not relevant to a written description requirement. To the contrary, all that is needed to comply with the written description requirement of the first paragraph of § 112 is that the biological material deposited be specifically identified in the application for patent as filed. M.P.E.P. 2406.01. Indeed, the M.P.E.P. provides that "[t]he requirement for a specific identification is consistent

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with the description requirement of the first paragraph of 35 U.S.C. 112 and provides an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." M.P.E.P. 2406.01.

Applicants' specification provides a clear written description of the λ-J19 proviral clone. For example, Figure 2 provides the restriction map of the λ-J19 clone. Furthermore, at page 10, lines 20-31, applicants describe the restriction sites for the λ-J19 clone. Finally, the actual deposit information for λ-J19 is specifically provided at page 14, line 23-27. Accordingly, applicants submit that the lack of adequate written description rejection is improper and withdrawal of the rejection is respectfully requested.

In response to the contention that applicants are entitled only to the priority date of S.N. 06/706,562, filed February 28, 1985, applicants respectfully disagree. However, regardless of the priority date to which applicants are entitled, such assertion is immaterial to the written description requirement of § 112. Applicants submit that the written description requirement relates to the instant application and as stated above, has been met by the literal support found in applicants' instant application.

Applicants acknowledge with appreciation the withdrawal of the rejection of claim 23 under 35 U.S.C. § 102(b) over Putney et al. and the withdrawal of the rejection of claims 23, 32, and 33 under 35 U.S.C. § 102(b) over Luciw et al.

Claims 23,.32, and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Luciw et al.

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It is stated that Luciw et al. describe the identification, characterization, and complete nucleotide sequence analysis of the full-length molecular clone of the AIDS virus, designated ARV-2. The *gag*, *pol*, and *env* genes were disclosed and the expression and purification of the Gag, Pol, and Env proteins were described. The reference is further cited to teach that antigenic HIV polypeptides can be used as immunogens. Luciw et al. do not disclose methods for the production of antibodies directed against antigens expressed against the λ-J19 restriction fragments of the claimed invention. Regardless of this deficiency, however, the rejection asserts that one of ordinary skill in the art would readily acknowledge that these different clones are obvious variants and that antigens expressed from different isolates could reasonably expect to have the same or similar immunogenic and antigenic properties. Applicants respectfully traverse the rejection.

To properly make a rejection under 35 U.S.C. § 103, the Examiner has the initial burden of establishing a *prima facie* case of obviousness. Meeting this burden requires the Examiner to show first that the prior art would have suggested to those of ordinary skill in the art that they should carry out the claimed process. Second, the Examiner must establish that the prior art would have revealed that in carrying out the process, those of ordinary skill in the art would have had a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be found in the prior art, not in applicants's disclosure. In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

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The claimed invention is directed to methods of producing antibodies to an antigen of HIV-1, wherein the antigens of HIV-1 are encoded by specific nucleic acid fragments of plasmid λ-J19. None of the restriction fragments of the λ-J19 plasmid are taught or suggested by Luciw et al. Instead, Luciw et al. merely describe the ARV-2 isolate and the coding regions for the Gag, Env, and Pol polypeptides. However, this teaching is insufficient to render specific restriction fragments of the λ-J19 for use as antigens in the claimed method of producing antibodies obvious.

Rather, applicants' invention specifically provides that the nucleic acid fragments extending from the restriction site *Kpn*I at about coordinate 6100 to the restriction site *Bgl*II at about coordinate 9150 of plasmid λ-J19; extending from the restriction site *Kpn*I at about coordinate 3500 to the restriction site *Bgl*II at about 6500 of plasmid λ-J19; and extending from the restriction site *Pst*I at about coordinate 800 to the restriction site *Kpn*I at about coordinate 3500 of plasmid λ-J19 are used for the step of providing an antigen of HIV-1 in the claimed method. On the other hand, the Luciw et al. reference does not teach these specific restriction fragments nor does it teach the plasmid λ-J19.

Moreover, in order to arrive at the claimed invention based upon the teachings of Luciw et al., one having ordinary skill in the art would have to modify the sequences of the ARV-2 *env*, *gag*, and *pol* regions and then, obtain specific restriction fragment sites as claimed herein. However, the motivation to make such modifications for the specific purpose of providing an antigen of HIV-1 is not suggested or supported by Luciw et al as required. In re Fritch, 23

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U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). Accordingly, applicants respectfully submit that the suggested modification of the cited prior art is not based upon the requisite motivation and the rejection is improper. Withdrawal of the rejection is respectfully requested.

Claims 23, 32, and 33 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hobson et al. in view of Hurn et al.

Hobson et al. teach the complete genome of LAV. It is stated that this sequence appears to be identical to that disclosed in the λ-J19 proviral clone. Moreover, the location, size, and coding region for the *gag*, *pol*, and *env* genes were identified. The precise restriction fragments and the methods for generating immunological reagents as claimed by applicants are not taught by Hobson et al. In order to remedy this deficiency, Hurn et al. is cited to describe art-recognized methods for the generation of immunological reagents. It is concluded that it would have been *prima facie* obvious to one having ordinary skill in the art at the time the claimed invention was made to employ λ-J19 restriction fragments corresponding to the *gag*, *pol*, and *env* coding regions to express HIV-1 viral antigens and employ these antigens for the production of HIV-1-specific antibodies. Applicants respectfully traverse the rejection.

The Hobson et al. reference describes the complete DNA sequence of LAV. However, this reference fails to teach the restriction fragments of the claimed invention. Indeed, the reference fails to provide a restriction map of the λ-J19 proviral clone at all, whereas the claimed invention is directed to the use of specific restriction fragments of the λ-J19 proviral clone. More specifically, applicants' claims specifically provide that the nucleic acid fragments

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extending from the restriction site *Kpn*I at about coordinate 6100 to the restriction site *Bgl*II at about coordinate 9150 of plasmid λ-J19; extending from the restriction site *Kpn*I at about coordinate 3500 to the restriction site *Bgl*II at about 6500 of plasmid λ-J19; and extending from the restriction site *Pst*I at about coordinate 800 to the restriction site *Kpn*I at about coordinate 3500 of plasmid λ-J19 are used in the claimed method. In contrast, the Hobson et al. reference teaches the locations and sizes of the viral open reading frames in Table 1. Based upon Table 1, the locations and sizes of the viral open reading frames are not similar to applicants' restriction fragments. Accordingly, the structural motivation to render the claim-recited restriction fragments obvious over the open reading frames disclosed in Hobson et al. is absent. In addition, the reference fails to motivate one having ordinary skill in the art to use anything other than the specific nucleotide fragments set forth in Table 1, which do not appear to correlate with the claim-designated restriction fragments. Therefore, applicants submit that the reference lacks the motivation to render the claimed invention obvious.

Hurn et al. fail to remedy the deficiencies of the Hobson et al. reference. This secondary reference is directed to general teachings regarding the production of antibodies using antigens. However, this reference does not teach the antigens, i.e., the restriction fragments, of the claimed invention. Furthermore, it does not provide the requisite motivation to modify the nucleotide sequences of the open reading frames as described by Hobson et al.

Therefore, in the absence of a suggestion to modify the complete DNA sequence of the LAV genome in order to obtain the restriction fragments of the claimed invention, applicants

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respectfully submit that the rejection fails to make a *prima facie* case of obviousness over the Hobson et al. and Hurn et al. Applicants respectfully request the withdrawal of the instant rejection.

For the foregoing reasons, applicants believe that this application is now in condition for allowance. In the event the Examiner disagrees, he is invited to call the undersigned to discuss the remaining issues.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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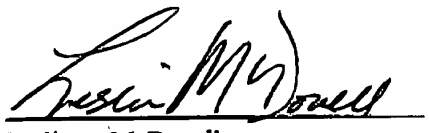
By: 
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Dated: July 2, 1997

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